



# Department of Justice

FOR IMMEDIATE RELEASE  
WEDNESDAY, SEPTEMBER 2, 2009  
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**REMARKS AS PREPARED FOR DELIVERY BY ASSISTANT ATTORNEY  
GENERAL TONY WEST AT PFIZER SETTLEMENT PRESS CONFERENCE**

WASHINGTON, D.C.

Thank you, Secretary Sebelius, and thank you for your leadership on this issue.

My name is Tony West and I'm the Assistant Attorney General for the Civil Division here at the Department of Justice. Today's announcement represents the largest criminal and civil settlement of a health care fraud case in U.S. history. This landmark, \$2.3 billion settlement with Pfizer and its subsidiary, Pharmacia & Upjohn Company, is important not just because it includes a record \$1.3 billion in criminal fine and forfeiture; and not just because Pfizer has agreed to pay \$1 billion to resolve serious civil fraud allegations, including over \$300 million to the states.

This case is important because of what it says about the U.S. Government's coordinated efforts to combat health care fraud and what those efforts mean to millions of Americans who rely on the integrity of programs like Medicare and Medicaid for the health care they need. Today's settlement demonstrates that health care fraud is a top priority for the Civil Division and the Department of Justice, and that when it comes to marketing drugs that so many of us rely on, we will expect companies to be honest in the claims they make about the drugs they sell.

This civil settlement and plea agreement represent yet another example of what penalties will be faced when a pharmaceutical company puts profits ahead of patient health. Illegal conduct and fraud like the allegations in this case puts the public health at risk, corrupts medical decisions by health care providers, and costs the government billions of dollars.

But it's not just the government who pays more. When health care fraud occurs, that drives the cost of health care up for all of us. Consumers pay higher premiums. Companies pay more to cover their employees. And every Medicare and Medicaid dollar lost to fraud means that fewer children will see doctors for preventable childhood diseases; more seniors will be faced with the stark choice between food or medicine at month's end; and fewer people will get the health care they need to dramatically improve the quality of their lives.

That's why settlements like today's are important: not only do they protect consumers, they also bring money lost to fraud back to public health programs, especially Medicare and Medicaid.

Today's settlement was made possible by two things: tough enforcement tools and terrific teamwork.

First, the tools: the Department of Justice has strong enforcement tools that help us work everyday to ensure that taxpayers are protected from fraud. On the civil side, we used the False Claims Act, which has allowed the Civil Division, working with US Attorneys around the country, to recover over \$14 billion from fraud against federal health care programs since 1986. Here, Pfizer has agreed to pay over \$650 million to resolve allegations under the civil False Claims Act that the company illegally promoted four drugs, using false and unsubstantiated claims regarding their safety and effectiveness, and caused federal health care programs to pay millions of dollars for prescriptions that were not for medically accepted uses.

In addition, the investigation of Pfizer began in 2003 with a whistleblower who filed a qui tam action under the False Claims Act, demonstrating the importance of the qui tam provisions in uncovering fraud in government programs.

We also used the Anti-Kickback statute to put an end to Pfizer's practice of paying kickbacks to health care providers to induce them to prescribe many of Pfizer's drugs. Patients must have confidence that their doctors are giving them the best medicines for the right reasons.

On the criminal side, the Civil Division's Office of Consumer Litigation used the Food, Drug, and Cosmetic Act which requires that companies specify the intended uses of a product in its new drug applications to FDA. Once a drug is approved for an intended use, it may not be marketed or promoted for so-called "off-label" uses – that is, any use not specified in the application and approved by FDA.

Now, in this case, Pfizer asked the FDA if it could promote the sale of Bextra, an anti-inflammatory drug, for certain other uses and in dosages higher than the maximum approved by FDA. The FDA, citing safety concerns, said no. But Pfizer marketed Bextra for those unapproved uses anyway.

When off-label marketing like this occurs, patients' health and lives are at risk, and those who cause that risk must be held accountable.

Second, the teamwork: without working together – across agencies and state lines – this settlement would not have been possible. The partnership that has developed among the various agencies, the U.S. Attorneys and numerous state and local law enforcement officials has recently led to several substantial health care fraud enforcement actions, prosecutions and recoveries. So I want to thank our law enforcement partners for

their continued commitment to ensuring that the integrity of our public health care programs is protected and I'm proud to stand with them this morning.

Now, it's my pleasure to introduce the Acting United States Attorney for the District of Massachusetts, Michael Loucks.

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